REMARKS

Claims 1-53 are pending in the instant application. Claims 1-53 have been rejected by the Examiner.

By the above amendments, Claims 31, 33, 34 and 48 has been amended and new Claims 54-63 have been added to more particularly point out and distinctly claim the subject matter which Applicants regard as the invention. More specifically, Claims 31 and 48 have been amended to more particularly point out that the dosage form is a high dose, osmotic dosage form comprising topiramate, wherein the topiramate is released from the dosage form at a substantially ascending release rate for a prolonged period of time. Additionally, Claims 33 and 34 have been amended to correct dependency. Support for new Claims 54-63 may be found throughout the specification, for example, in paragraphs [00021]-[00023] and [00099]-[000100], of the specification. Applicants submit that the amendment are fully supported by the specification as filed, and that no new matter is being added.

By the above amendments, Claims 1-30, 32 and 38-47 have been canceled without prejudice. Applicants submit that the amendments canceling Claim 1-30, 32 and 38-47 are being made solely to advance the prosecution of the instant application and are not in any way to be construed as an admission that the Canceled material is unpatentable. Thus, Applicants reserve the right to pursue coverage of the canceled material by filing a continuation or a divisional application at an appropriate time in the future.

After entry of the amendments, Claim 31, 33-37 and 48-63 will remain pending and under consideration. Reconsideration of the captioned application based on the previous amendments and following remarks is respectfully requested.

The Examiner has provisionally rejected Claims 1-53 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1-34 of co-pending Application No. 11/024,329. Applicants respectfully submit that they will be able to address this issue upon an indication that the pending claims are otherwise deemed to be in condition for allowance.

The Examiner has provisionally rejected Claims 1-53 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1-21 of co-pending Application No. 11/024,330. Applicants respectfully submit that they will be able to address this issue upon an indication that the pending claims are otherwise deemed to be in condition for allowance.

The Examiner has provisionally rejected Claims 1-53 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1-27 and 32-39 of co-pending Application No. 11/024,378. Applicants respectfully submit that they will be able to address this issue upon an indication that the pending claims are otherwise deemed to be in condition for allowance.

The Examiner has rejected Claims 28 under 35 U.S.C. §112, second paragraph as allegedly indefinite, for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicants respectfully refer the Examiner to the above amendments canceling Claims 1-30, 32 and 38-47 which render the rejection moot. Applicants therefore respectfully request that the rejection of Claim 28 under 35 U.S.C. §112, second paragraph be withdrawn.

The Examiner has rejected Claims 2-5, 7, 8, 11, 12, 14, 15 under 35 U.S.C. §102(b) as being allegedly anticipated by WO99/44581.

Applicants respectfully refer the Examiner to the above amendments canceling Claims 1-30, 32 and 38-47 which render the rejection moot. Applicants therefore respectfully request that the Examiner withdraw rejection of Claims 2-5, 7, 8, 11, 12, 14 and 15 under 35 U.S.C. §102(b) as anticipated by WO99/44581.

The Examiner has rejected Claims 2, 6-9, 11, 12 and 14-21 under 35 U.S.C. §102(e) as allegedly anticipated by Louie-Helm et al. US 2003/0091630.

Applicants respectfully refer the Examiner to the above amendments canceling Claims 1-30, 32 and 38-47 which render the rejection moot. Applicants therefore

respectfully request that the rejection of Claim 2, 6-9, 11, 12 and 14-21 under 35 U.S.C. §102(e) as anticipated by Louie-Helm et al., US 2003/0091630 be withdrawn.

The Examiner has rejected Claims 2-5, 14-19, 22, 25, 26, 28 and 29 under 35 U.S.C. §102(e) as allegedly anticipated by Almarsson et al. US 6,699,840 B2.

Applicants respectfully refer the Examiner to the above amendments canceling Claims 1-30, 32 and 38-47 which render the rejection moot. Applicants therefore respectfully request that the Examiner withdraw the rejection of Claims 2-5, 14-19, 22, 25, 26, 28 and 29 under 35 U.S.C. §102(e) as anticipated by Almarsson et al. US 6,699,840 B2.

The Examiner has rejected Claims 1-9 and 11-21 under 35 U.S.C. §103(a) as allegedly unpatentable over Louie-Helm et al US2003/0091630. More specifically, the Examiner states that Louie-Helm disclose a dosage form comprising topiramate in the form of compressed tablets that contain an erodible, swellable matrix along with the active ingredient.

Applicants respectfully refer the Examiner to the above amendments canceling Claims 1-30, 32 and 38-47 which render the rejection moot. Applicants therefore respectfully request that the rejection of Claims 1-9 and 11-19 under 35 U.S.C. §103(a) over Louie-Helm et al US2003/0091630 be withdrawn.

The Examiner has rejected Claims 1-21 under 35 U.S.C. §103(a) as allegedly unpatentable over Louie-Helm et al US2003/0091630 in view of Berner et al., US 6,488,962.

Applicants respectfully refer the Examiner to the above amendments canceling Claims 1-30, 32 and 38-47 which render the rejection as it relates to Claims 1-21 moot. Applicants therefore respectfully request that the Examiner withdraw the rejection of Claims 1-21 under 35 U.S.C. §103(a) over Louie-Helm et al US2003/0091630 in view of Berner et al. US 6,488,962.

The Examiner has rejected Claims 1-9 and 11-53 under 35 U.S.C. §103(a) as allegedly unpatentable over Almarsson et al. US 6,699,840 B2. More specifically, the Examiner states that "Almarsson discloses oral dosage forms of topiramate with excipients, such as polyvinyl pyrrolidone and hydroxypropylmethylcellulose..."; that "[s]uch dosage forms are formulated using hydroxypropylmethyl cellulose, and osmotic systems, such as OROS®..."; and that "[t]he reference teaches the amount of topiramate in the composition can range from 10 mg – 1000 mg...". The Examiner concludes that "[t]he generic invention is embodied and described by Almarrasson."

Applicants respectfully refer the Examiner to the above amendments canceling Claims 1-30, 32 and 38-47 which render the rejection as it relates to Claims 1-9, 11-30, 32 and 38-47 moot. Applicants therefore will respond to the rejection only as it relates to Claim 31 and 48-53.

Applicants respectfully traverse the rejection. Applicants submit that the present invention is directed to high dose osmotic dosage forms and methods of use which comprise administration of said high dose osmotic dosage forms; wherein the dosage form comprises a composition containing about 50-60% topiramate and about 15-40% solubilizing surfactant, and wherein the topiramate is released at a substantially ascending rate of release for a prolonged period of time. Applicants further submit that in the present invention it was unexpectedly found that the use of about 15-40% solubilizing surfactant permits the formulation of topiramate, a low solubility drug, at the high loading levels of 50-60%, thereby permitting the formulation of the high dosage forms of the present invention.

Applicants submit that Almarsson et al., do not teach or suggest the specific percentages of topiramate, structural polymer carrier and, solubilizing surfactant required to make the high dose osmotic dosage forms of the present invention. Applicants therefore maintain that one skilled in the art in reading Almarsson et al. would not be motivated to make the formulations of the present invention. Applicants therefore respectfully request that the rejection of Claims 1-9 and 11-53 under 35 U.S.C. §103(a) Almarsson et al. US 6,699,840 B2 be withdrawn.

The Examiner has rejected Claims 1, 31 and 38 under 35 U.S.C. §103(a) as allegedly unpatentable over Bhatt et al., US 6,368,626. More specifically, the Examiner states that "Bhatt teaches the same surfactants and structural polymers as claimed by Applicants...", that "[t]he reference also discloses a push layer ... a drug loading between 20-90% by weight ... use of a structural polymer between 1-90%..." and that "...in Example 1 the composition contains approx. 30% surfactant and 69% active agent. This is a ratio of approx. 1:2..." The Examiner concludes that "[o]ne of ordinary skill in the art would be able to determine through routine experimentation the reasonable amount of surfactant to add to maintain the desired ratio and achieve the desired release profile."

Applicants respectfully traverse the rejection. Applicants submit that Bhatt et al. disclose push-stick osmotic dosage forms, wherein the drug layer is released in a dry or substantially dry form (i.e. in plug form). Although Bhatt et al. discloses a long list of drugs, including anticonvulsants, which may be formulated within the push-stick osmotic dosage forms, Bhatt et al. does not teach or suggest formulations or dosage forms comprising topiramate as the active agent.

Applicants further submit that in the present invention it has unexpectedly been found that the use of 15-40% of solubilizing surfactant within the drug containing composition increases the solubility of topiramate, thereby permitting the formulation of the dosage forms for administration of high doses of topiramate. Applicants further maintain that the use of about 15-40% solublizing surfactant promotes dissolution and suspension of the topiramate for optimal performance (see for example, paragraph [00018], [00023] and [00088] of the specification). Thus, in the present invention, the drug layer containing the topiramate is dissolved and / or suspended when released from the dosage form, and is therefore <u>not</u> released in a dry or substantially dry form.

Applicants maintain that the disclosure in Bhatt et al. of a dosage form which releases the active agent in a dry or substantially dry form would not motivate one or ordinary skill in the art to make the dosage forms of the present invention. Applicants therefore respectfully request that the rejection of Claims 1, 31 and 38 under 35 U.S.C. §103(a) as allegedly unpatentable over Bhatt et al., US 6,368,626 be withdrawn.

The Examiner has rejected Claims 1-53 under 35 U.S.C. §103(a) as allegedly unpatentable over Almarsson et al US6,699,840 in view of Bhatt et al US 6,368,626. More specifically, the Examiner states that Almarsson et al disclose oral dosage forms of topiramate including osmotic systems, such as OROS®; that Bhatt et al teach the same surfactants and structural polymers as claimed by Applicant and that in Example 1 Bhatt et al. disclose a composition that contains approx. 30% surfactant and 69% the active agent. The Examiner concludes that "[i]t would be obvious to one of ordinary skill to use the dosage forms disclosed by Bhatt to make a controlled release osmotic dosage form of topiramate because Almarsson suggests and teaches to do so."

Applicants respectfully traverse the rejection. Applicants submit that neither Almarsson et al., nor Bhatt et al., teach or suggest the use of about 15-40% solubilizing surfactant in conjunction with a low solubility drug, such as topiramate, for the purpose of preparing a high dose osmotic dosage form, wherein the topiramate is released with a substantially ascending release rate for a prolonged time. Applicants further maintain that as discussed in more detail above, the percentages by weight of topiramate and the percentages by weight of the solubilizing surfactant required for the preparation of a high dose osmotic dosage form which releases the topiramate with a substantially ascending rate of release for a prolonged period of time would not fall within the scope of routine experimentation.

Applicants therefore respectfully request that the Examiner withdraw the rejection of Claims 1-53 under 35 U.S.C. §103(a) as allegedly unpatentable over Almarsson et al. US 6,699,840 in view of Bhatt et al. US 6,368,626.

The Examiner has rejected Claims 1-53 under 35 U.S.C. §103(a) as allegedly unpatentable over Faour et al. US 6,491,949 in view of Almarsson et al US 6,699,840. More specifically, the Examiner states that "Faour discloses an osmotic delivery device..."; that "Faour teaches the structural limitations of the dosage form with the exception of the particular active ingredient."; and that "Almarsson teaches the use of topiramate in an osmotic delivery device." The Examiner concludes "It would have been obvious to one of ordinary skill in the art to make an osmotic delivery device offering controlled release of an active substance such as topiramate ..."

Applicants respectfully traverse the rejection. Applicants submit that Faour et al., in US 6,491,949 disclose a dual osmotic device comprising a first osmotic device enclosed within a second osmotic device wherein the first drug layer and the second drug are separated by a semi-permeable membrane and wherein the rate of release of the first drug layer and the rate of release of the second drug layer are achieved by differences in the type and amount of semi-permeable layer present. In additionally disclosed embodiments, Faour et al. teach that the chemical and physical integrity of the first and / or second semi-permeable membrane is lost, thereby controlling the rate of release of the osmotic device. Applicants submit that Faour et al. do not teach or suggest the high dose osmotic dosage forms of the present invention, wherein the drug layer comprises about 50-60% topiramate and about 15-40% solubilizing surfactant and wherein the topiramate is released with a substantially ascending rate of release over a prolonged period of time (without use of a semi-permeable membrane which controls the release rate of the drug by loss of it chemical and physical integrity).

Applicants further submit that while Almarsson et al. disclose the formulation of topiramate in osmotic dosage forms, Almarsson et al. do not teach or suggest the specific percentages by weight of the topiramate and the solubilizing surfactant present in the high dose osmotic dosage forms of the present invention.

Applicants further maintain that one skilled in the art in reading Faour et al. and Almarsson et al., either alone or in combination, would not be motivated to make the claimed dosage forms containing the specified percentages of topiramate and solubilizng surfactant. Applicants submit that topiramate is a low solubility drug and that in the present invention it was unexpectedly found that for administration of high doses of topiramate, formulating the drug containing composition with about 15-40% solubilizing surfactant results in enhanced solubility of the topiramate so as to permit formulation of the dosage form for high doses, with a substantially ascending release rate for a prolonged period of time (see for example, paragraphs [00023], [00088] and [00100] of the specification). Applicants maintain that the selection of these components and percentages would not be obvious to one of ordinary skill in the art in reading Faour et al. and Almarsson et al., either alone or in combination, and further, would not fall within routine experimentation.

Applicants therefore respectfully request that the Examiner withdraw the rejection of Claims 1-53 under 35 U.S.C. §103(a) as allegedly unpatentable over Faour et al. US 6,491,949 in view of Almarsson et al US 6,699,840.

In view of the above amendments and remarks, Applicants maintain that the application is in condition for allowance and passage to issue is earnestly requested.

Respectfully submitted,

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